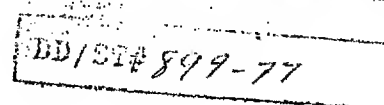
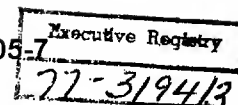


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ORD 322-77

28 FEB. 1977

MEMORANDUM FOR: Acting Director of Central Intelligence

FROM : Leslie C. Dirks
Deputy Director for Science and Technology

SUBJECT : Guidelines for Human Subject Research

REFERENCE : A. ADCI Memorandum #77-3194/1,
dated 25 January 1977.
B. DD/S&T Memorandum #437-77,
dated 27 January 1977.
C. Proposed DCID 9/1

1. The CIA Human Subject Guidelines Working Group met on 31 January and 7 February to develop a coordinated CIA position with respect to the establishment of guidelines for human subject research. The Working Group specifically considered possible errors and omissions in the recommendations put forth by the I.C. Staff in proposed DCID 9/1.

2. The Working Group recommends that no Community-wide directive be promulgated at this time. This recommendation is made for the following reasons:

a. The academic and biomedical communities have experienced difficulty with the practical implementation of DHEW Guidelines (45 CFR 46). Particular problems have emerged with regard to operation of Institutional Review Boards (IRB's). This has occurred despite the fact that 45 CFR 46 reflects ethical principles shared, in the broad sense, by the U.S. scientific community.

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b. In recognition of these difficulties the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has scheduled nationwide public hearings to review the performance of IRB's. (We note that sections 202 (a)(3) and 204 (b) of PL 93-348 permit the National Commission to investigate the human subject research practices of the CIA and make recommendations to Congress for their revision):

(1) The hearings are planned in order to identify unnecessary impediments to the conduct of research and possible shortcomings in the protection of human subjects.

(2) Public hearings are currently scheduled to be held in Chicago (5 April 1977), San Francisco (15 April 1977), and Bethesda (3 May 1977).

c. Successful implementation of any Community-wide directive dealing with human subject research rests, to a very great extent, on the proper functioning of IRB's. The Working Group recognizes that Intelligence Community IRB's will face not only those problems already encountered by the academic and biomedical communities, but additional difficulties caused by the need to adapt DHEW Guidelines to novel security and management constraints.

d. Since the CIA has no previous experience with the operation of its own IRB's, but is aware of difficulties faced by the academic and biomedical communities as well as the concern demonstrated by the National Commission, the Working Group is reluctant to recommend adoption of a Community-wide directive until it can evaluate the success of the Agency's own efforts in this matter (see paragraph 3).

e. The Working Group, however, is prepared to meet with representatives of the IC Staff to cooperate in the development of Community Guidelines which reflect the ethical principles enunciated by DHEW, appropriate recommendations of the National Commission, restrictions imposed by E.O. 11905, legitimate concerns regarding the protection of intelligence sources and methods, and the experience gained by elements within the Community in the conduct of human subject research.

3. The Working Group strongly recommends adoption of the attached guidelines developed at its working sessions, and promulgation of corresponding internal regulations, to cover the research activities of the CIA involving human subjects at risk. By so doing we:

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- a. Insure that CIA research activities adhere strictly to Guidelines promulgated by DHEW and reflect recommendations made by the National Commission.
- b. Incorporate additional restrictions imposed on Agency activities by E.O. 11905 that were not reflected in the I.C. Staff recommendation.
- c. Avoid the use of procedures which go beyond those recommended by DHEW, The National Commission, and E.O. 11905.
- d. Provide adequate protection for intelligence sources and methods.
- e. Will cause the creation of Agency IRB's to review in-house research projects and develop procedures for the evaluation of foreign research activities.
- f. Specifically identify the differing responsibilities of the CIA and its contractors in protecting the rights and welfare of human subjects. The Working Group's recommendations parallel, precisely, those policies adopted by DHEW in dealing with organizations receiving their financial support.
- g. Pave the way for more rapid implementation of human subject guidelines within the Agency. No challenge has yet been raised to the authority of the DCI to promulgate guidelines, within the CIA, covering the full range of human subject research activities.

STAT



LESLIE C. DIRKS
Deputy Director
for

Science and Technology

Attachments:

- A. Coordinated proposal for CIA Human Subject Guidelines w/atts I & II
- B. Proposed DCID 9/1 w/att III
- C. OGC memoranda concerning authority of DCI. (2)

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77-3194/4

CENTRAL INTELLIGENCE AGENCY

HUMAN SUBJECT GUIDELINES

Pursuant to Section 102 of the National Security Act of 1947, Executive Order 11905, and National Security Council Intelligence Directives, a policy is hereby established for the protection of human subjects of research activities conducted or funded by the CIA.

1. Purpose

The purpose of this document is to provide policy guidance to assure that research involving human subjects at risk, conducted or funded by the Central Intelligence Agency, will be in accordance with:

- a. ethical concerns for the preservation of human life, rights, and dignity,
- b. all applicable statutes, applicable Executive Branch directives, and applicable agency or department regulations, and
- c. the procedures which are established to protect intelligence sources, methods, or data in research.

2. General Guidance

a. Protection of Research Subjects

(1) The Department of Health, Education and Welfare (DHEW) Guidelines and Regulations (45 CFR 46 - Protection of Human Subjects, revised 1 October 1976), portions of which include recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, shall represent the minimum acceptable standards governing the treatment of human research subjects. (Attachment I)

(2) § 46.103 (C) (5) is interpreted to mean: An offer to answer any inquiries concerning the procedures not inconsistent with either the experimental design or security considerations.

(3) To receive funding from the CIA, an approved assurance must be obtained from the DHEW/Office of Protection from Research Risks, by the organization proposing to conduct the research effort.

(4) The organization conducting the research assumes responsibility for: (a) compliance with 45 CFR 46 (rev. 1 Oct 76), all applicable statutes, and those Executive Branch directives and agency or department regulations supplied by the CIA; and (b) providing adequate protection for the rights and welfare of human subjects at risk.

(5) Experimentation with drugs on human subjects will, in addition, be subject to restrictions imposed by E.O. 11905 section 5(d). (Attachment II)

(6) If, in the judgment of the CIA, an institution has failed materially to comply with the terms of this policy statement with respect to a particular contract or grant, the CIA may require that said contract or grant be terminated in the manner prescribed in applicable contract or procurement regulations.

b. Protection of Intelligence Sources, Methods, or Data

Only those individuals possessing appropriate security clearances and signing secrecy non-disclosure agreements may be provided with classified information appropriate to the research study.

3. Applicability

a. Data collected in the normal course or as a by-product of approved administrative or operational actions, and therefore not subject to the policy guidelines stated herein, may subsequently be made available for use in formal research projects if adequate safeguards are provided to preserve subject confidentiality.

b. The procedures described in the preceding paragraphs apply to all human subject research, involving U.S. persons at risk, funded or conducted by the Central Intelligence Agency.

STANSFIELD TURNER
Admiral, U.S. Navy
Director of Central Intelligence

Attachment I

CODE OF FEDERAL REGULATIONS

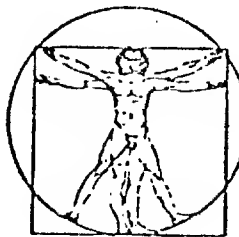
TITLE 45

PUBLIC WELFARE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

REVISED AS OF NOVEMBER 6, 1975

CORRECT TO 1 OCT '76



PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A

- Sec.
- 46.101 Applicability.
 - 46.102 Policy.
 - 46.103 Definitions.
 - 46.104 Submission of assurances.
 - 46.105 Types of assurances.
 - 46.106 Minimum requirements for general assurances.
 - 46.107 Minimum requirements for special assurances.
 - 46.108 Evaluation and disposition of assurances.

(Cont'd)

THURSDAY, FEBRUARY 19, 1978 *22*

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*see also for
concrete request
during open meeting*

Attachment II

PART III:

THE PRESIDENT

UNITED STATES FOREIGN INTELLIGENCE ACTIVITIES

Executive Order 11905

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WORKING GROUP EVALUATION OF PROPOSED DCID 9/1

Proposed DCID 9/1:

1. Contains errors of fact. The attachment to the proposed DCID, which purports to summarize key elements of the DHEW Human Subject Guidelines, is found to be inaccurate and misleading when compared with the actual DHEW guidelines, 45 CFR 46 (rev. 1 Oct 76).
2. Does not provide interpretation of 45 CFR 46 (rev. 1 Oct 76) where necessary to protect the interests of security or preserve the validity of experimental procedures.
3. Does not incorporate restrictions imposed on the Intelligence Community by E.O. 11905 with regard to drug experimentation.
4. Adopts procedures that go beyond those recommended by DHEW, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and E.O. 11905.
5. Does not specifically indicate who is responsible for protecting the rights and welfare of human subjects at risk. Note that DHEW policy (§ 46.102 (a), (b)(2), (e)) places primary responsibility on the institution which receives or is accountable for the funds awarded in support of the research activity.
6. Does not protect intelligence sources and methods. It raises unnecessarily the question of project sponsorship and does not consider the use of clandestine resources.

DIRECTOR OF CENTRAL INTELLIGENCE DIRECTIVE NO. 9/1

GUIDELINES FOR HUMAN SUBJECT RESEARCH
WITHIN THE INTELLIGENCE COMMUNITY

(Effective

Pursuant to Section 102 of the National Security Act of 1947, Executive Order 11905, and National Security Council Intelligence Directives, a policy is hereby established for the protection of human subjects in research undertaken or sponsored by the Intelligence Community.

1. Purpose

Purpose is really meaningless

The purpose of this directive is to provide policy guidance to the Intelligence Community to assure that research conducted or sponsored by any element of the Community that makes use of human subjects will be in accordance with:

- a. principles and criteria recognized by the applicable professions as a requisite for scientifically valid and ethical research. — *most professions have never enunciated ethical guidelines*
- b. ethical concerns for the preservation of human life, rights, and dignity,
- c. all applicable statutes, Executive Branch directives, and agency or department regulations, and
- d. the procedures which are established to protect intelligence sources, methods, or data in research.

2. General Guidance

The following guidelines shall apply to all research undertaken or sponsored by Intelligence Community organizations, which makes use of human research subjects:

a. Protection of Research Subjects

(1) The Department of Health, Education and Welfare (DHEW) Guidelines and Regulations, portions of which include the recommendations of the National Commission for the Protection

prohibition of EO 11905 Section (5) d on drug

8 February 1977

ATTACHMENT

MEMORANDUM FOR: General Counsel

FROM :
Assistant General Counsel

SUBJECT : Proposed DCID 9/1, "Guidelines for Human Subject
Research Within the Intelligence Community"

1. This Office has received a copy of the proposed DCID which is referenced above, indicating that the DCID has been sent to the National Foreign Intelligence Board for comment and/or concurrence. In addition we have been directed to participate in a working group which is formulating a coordinated CIA response to the proposed DCID.

2. I believe it may be advisable to re-state our concern regarding this DCID, a concern which we put on record during the initial coordination process for the documents.

3. That is, I believe it is doubtful whether the DCI has the authority to provide comprehensive direction on all points covered by the proposed DCID.

4. Certainly there is no question of the DCI's authority to act with respect to that part of the proposed DCID which addresses the protection of intelligence sources and methods. However we find no direct authority enabling the DCI to give direction or set standards for the protection of human research subjects, except in his role as Director of the Central Intelligence Agency.

5. Executive Order 11905 does not provide the DCI with this authority. No basis for it is contained within subsection 3(d) of the Order, which sets out duties of the Director of Central Intelligence Section 5 of the Order, which sets out restrictions on intelligence activities, contains a restriction pertaining to human research subjects, but it is specifically limited to experimentation with drugs. Moreover, this statement issues directly from the President.

STAT

1-1-77
Adm-13.1 P.H.
561-77

25 January 1977

MEMORANDUM FOR: Deputy Director for Administration
Deputy Director for Operations
Deputy Director for Intelligence
✓ Deputy Director for Science & Technology
Office of the General Counsel

SUBJECT : Proposed DCID No. 9/1, Guidelines for Human Research
Within the Intelligence Community

A survey conducted by the Office of the DDI indicates that at least three of the Directorates believe that major and -- in some cases -- conflicting substantive revisions are needed.

For the purpose of developing a coordinated CIA position on this important and sensitive subject, I would like the DDS&T to chair a working group composed of representatives of each of the Directorates and the Office of the General Counsel. The Office of the DDI will make available to the working group copies of the comments prepared by each of the Directorates.

The working group should undertake this task as expeditiously as possible. I should like to submit the CIA position to the NFIB secretariat no later than 15 February.

[Redacted Signature]

E. H. Knoche

Acting Director of Central Intelligence

cc: Walter Elder (NFIB Secretariat)

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77-3194/2

Approved For Release 2004/02/19 : CIA-RDP80M00165A000500260005-7

DD/S&T-438-77 2-1121

27 January 1977

MEMORANDUM FOR: Acting Director of Central Intelligence

SUBJECT : Working Group to Review
Proposed DCID No. 9/1

REFERENCE : Memorandum from ADCI dtd 25 Jan 77
Same Subject

In accordance with your direction in the reference memorandum, I have selected [REDACTED]

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[REDACTED] to chair the Working Group you would like to have established for the purpose of reviewing the proposed DCID. I have instructed Joe to proceed forthwith to form the appropriate group with members drawn from the four Directorates and move ahead rapidly to meet the deadline of 15 February which you have established.

STAT

[REDACTED]

LESLIE C. DIRKS
Deputy Director
for
Science and Technology

77-3194/2 - 1.12.1

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E.R. copy

Executive Registry
77-3194/1

7

25 January 1977

MEMORANDUM FOR: Deputy Director for Administration
Deputy Director for Operations
Deputy Director for Intelligence
Deputy Director for Science & Technology
Office of the General Counsel

SUBJECT : Proposed DCID No. 9/1, Guidelines for Human Research
Within the Intelligence Community

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STAT



E. H. Knoche

Acting Director of Central Intelligence

cc: Walter Elder (NFIB Secretariat)

UNCLASSIFIED		CONFIDENTIAL		SECRET	
OFFICIAL ROUTING SLIP					
TO	NAME AND ADDRESS	DATE	INITIALS		
1	Active				
2	J. Lapham - See S. Hewens' 3rd para.				
3	Perhaps you want to put a note on				
4	this to Knoche since he is				
5	Chm/NFIB	RH, 1/24/77			
6	I haven't sent to Knoche yet!				
ACTION		DIRECT REPLY		PREPARE REPLY	
APPROVAL		DISPATCH		RECOMMENDATION	
COMMENT		FILE		RETURN	
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Remarks:					
FOLD HERE TO RETURN TO SENDER					
FROM: NAME, ADDRESS AND PHONE NO.					DATE
Deputy Director for Intelligence					1/24/77
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SENDER WILL CHECK CLASSIFICATION TOP AND BOTTOM					
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